

## **Section 2: Amendment to Claims:**

1. **(Amended)** A manual, single dosage-unit medication delivery system platform for targeted oral hygiene treatment of adverse periodontal conditions of bad breath and gingivitis present in oral soft gingival and sulcus tissues of persons affected by such conditions, consisting essentially of:

a) a sterile disposable cotton roll substrate of size and length for easy insertion, by said person in need of treatment of adverse periodontal conditions of bad breath and gingivitis present in oral soft gingival and sulcus tissues, into a buccal vestibule adjacent said tissues needing treatment as a targeted location and as a source for extended, targeted oral hygiene treatment delivery of medication, said cotton roll substrate is sized to be received and retained comfortably in said buccal vestibule, and said cotton roll substrate retains its integrity upon being massaged by a buccinator muscle adjacent said buccal vestibule for an extended period of treatment time of up to an hour;

b) a topical oral medication treatment composition effective to treat said adverse periodontal conditions carried by and releasably retained [absorbed] in said roll in an extended-release, single-use dosage amount in the range of .75 – 3 ml that is therapeutically effective to treat said adverse periodontal conditions; and

c) said substrate and treatment composition in combination, upon insertion and retention in said buccal vestibule for an extended period of time and upon massaging action by a buccinator muscle adjacent said buccal vestibule, effects release of a concentration of said treatment composition in a targeted location directly into contact with affected tissue, and said treatment composition is expressed and leaches from said substrate roll source over an extended treatment period to bathe said oral gingival and sulcus tissues, and to stimulate saliva production, thereby effecting treatment of said periodontal condition at said dosage amount[s] which is substantially lower than conventional mouthwash, and in a manner which does not interfere with or restrict ordinary life activities [, including] of speaking and moving around.

2. **(Previously Amended)** A medication delivery system for oral hygiene as in claim 1 wherein said medication is in a state selected from a liquid and a gel.

3. **(Previously Amended)** A medication delivery system for oral hygiene as in claim 2 wherein said composition is selected from an anti-microbial compound or composition, a

fluoride-ion providing compound or composition, an analgesic, an enzyme, a natural plant herb, oil or extract, an anti-plaque compound or composition, and combinations thereof, and said composition is present in said roll in an effective amount for amelioration of bad breath conditions.

**3. (Cancelled) A medication delivery system for oral hygiene as in claim 3 wherein said composition is an anti-microbial present in said roll in an effective amount for amelioration of bad breath conditions.**

**4. (Original)** A medication delivery system for oral hygiene as in claim 3 wherein said composition is a fluid and said fluid is present in an amount sufficient to substantially moisten or to saturate said cotton roll.

**5. (Previously Amended/Withdrawn)** A medication delivery system for oral hygiene as in claim 3 wherein said composition includes at least one active ingredient selected from a boric acid-containing and a benzoic acid-containing mouthwash.

**6. (Previously Amended)** A medication delivery system for oral hygiene as in claim 3 wherein said composition includes at least one active ingredient selected from: thymol; eucalyptol; methyl salicylate; menthol; ethyl alcohol; benzoic acid; sodium benzoate; boric acid; citric acid; calcium lactate; cetyl pyridinium chloride; tetrasodium pyrophosphate; benzalkonium chloride; domiphen bromide; sodium benzoate; eugenol; eucalyptus oil; aloe vera; oil of cloves; triclosan; chlorhexidine; chlorhexidine gluconate; sodium hypochlorite; sodium stannate; hydrogen peroxide; carbamide peroxide; antibiotics; analgesics; chlorine dioxide; zinc-containing compounds; fluoride ion-providing compounds; enzymes and enzymatic compounds selected from lysozyme, lactoferrin, glucose oxidase, and lactoperoxidase; copper gluconate; natural plant extracts having anti-microbial or therapeutic properties; and mixtures thereof.

**7. (Previously Amended)** A medication delivery system for oral hygiene as in claim 2 wherein said cotton roll has a diameter ranging from about 3/16" to about 7/16" and length ranging from about 1" to about 2".

**8. (Original)** A medication delivery system for oral hygiene as in claim 7 wherein said

cotton roll includes a core of absorbent cotton fibers and a sheath selected from a mesh braiding and a highly permeable woven or non-woven sheet material.

9. **(Original)** A medication delivery system for oral hygiene as in claim 8 wherein said cotton roll is a braided cotton roll having a diameter of about 5/16" and length of about 1 1/2", and each end is terminated in a transverse cut.

10. **(Amended)** A portable consumer package having therein a plurality of individual manual, single dosage-unit, medication delivery system units for targeted oral hygiene treatment of adverse periodontal conditions of bad breath and gingivitis present in oral soft gingival and sulcus tissues of persons affected by such conditions, comprising in operative combination:

a) a sealed, water impervious pouch having a manually openable seal member and which is sized to fit in a shirt pocket; and

b) a plurality of single use, disposable, medication-delivery units disposed in said pouch, each of which consists essentially of:

i) a sterile cotton roll substrate of size and length for easy insertion, by said person in need of treatment of adverse periodontal conditions of bad breath and gingivitis present in oral soft gingival and sulcus tissues, into a buccal vestibule adjacent said tissues needing treatment as a targeted location and as a source for extended, targeted oral hygiene treatment delivery of medication, said cotton roll substrate is sized to be received and retained comfortably in said buccal vestibule, said cotton roll substrate retains its integrity upon being massaged by a buccinator muscle adjacent said buccal vestibule for an extended period of treatment time of up to an hour; and

ii) a topical oral medication treatment composition in fluid or gel form in an amount effective to treat said adverse periodontal conditions carried by and releasably retained [absorbed] in said roll in an extended-release, single-use dosage amount in the range of .75 – 3 ml that is therapeutically effective to treat said adverse periodontal conditions; and

c) said substrate and treatment composition in combination, upon insertion and retention in said buccal vestibule for an extended period of time and upon massaging action by a buccinator muscle adjacent said buccal vestibule, effects release of a concentration of said treatment composition in a targeted location directly into contact with affected tissue, and said

treatment composition is expressed and leaches from said substrate roll source over an extended treatment period to bathe said oral gingival and sulcus tissues, and to stimulate saliva production, thereby effecting treatment of said periodontal conditions at said dosage amount[s] which is substantially lower than conventional mouthwash and in a manner which does not interfere with or restrict ordinary life activities[, including] of speaking and moving around.

11. (Previously Amended) A portable consumer package for oral hygiene treatment as in claim 10 wherein said pouch includes a manually reclosable seal member.

12. (Previously Amended) A portable consumer package for oral hygiene treatment as in claim 11 wherein said reclosable seal member includes a tear off strip and a zip-type closure that permits re-closing said pouch.

13. (Amended) A portable consumer package for oral hygiene treatment as in claim 10 which contains from 2 to 4 of said cotton rolls and wherein said composition is selected from an anti-microbial compound or composition, a fluoride-ion providing compound or composition, an analgesic, an enzyme, a natural plant herb, oil or extract, an anti-plaque compound or composition, and combinations thereof.

14. (Previously Amended) A portable consumer package for oral hygiene treatment as in claim 13 wherein said composition is a fluid and said fluid is present in an amount sufficient to substantially moisten or to saturate said cotton roll, said pouch ranges in width from about 1.75" to about 2.25" and in length from about 2 - 2 ½" and each said cotton rolls has a diameter ranging from about 3/16" to about 7/16", a length ranging from about 1" to about 2", a core of absorbent cotton fibers and a sheath selected from a mesh braiding and a highly permeable woven or non-woven sheet material.

15. (Original) A portable consumer package for oral hygiene treatment as in claim 10 wherein a plurality of said pouches are packaged in a box.

16. (Cancelled) ~~A method of targeted oral hygiene treatment comprising the steps of:~~

~~a) providing a single use disposable buccal insert, consisting essentially of: a~~

sterile cotton roll of size and length to be received comfortably in a buccal vestibule and having a topical oral medication treatment composition carried by said roll in a single-use dosage amount that is therapeutically effective to treat adverse periodontal conditions;

b) inserting a said treatment composition-carrying roll in a buccal vestibule for a time sufficient to provide some amelioration of said periodontal condition, so that upon action by a buccinator muscle, said treatment composition is expressed and leaches from said roll to bathe oral soft tissues, teeth surfaces and gingival sulcus, and saliva production is stimulated and reabsorbed by said roll, thereby effecting treatment of said periodontal condition; and

c) removing and disposing of said single-use cotton roll after substantial expression or leaching out of said treatment composition to the oral tissue and gingival sulcus;

17. (Cancelled) A method of oral hygiene treatment as in claim 16 wherein said composition is in a state selected from a liquid, a gel and a dry state.

18. (Cancelled) A method of oral hygiene treatment as in claim 17 wherein said composition is selected from an anti-microbial compound or composition, a fluoride ion-providing compound or composition, an analgesic, an enzyme, a natural plant herb or extract, an anti-plaque compound or composition, and combinations thereof.

19. (Cancelled) A method of oral hygiene treatment as in claim 18 wherein said composition includes at least one active ingredient selected from: thymol; eucalyptol; aloe vera; methyl salicylate; menthol; ethyl alcohol; benzoic acid; sodium benzoate; boric acid; citric acid; calcium lactate; cetyl pyridinium chloride; tetra sodium pyrophosphate; benzalkonium chloride; domiphen bromide; sodium benzoate; eugenol; eucalyptus oil; oil of cloves; triclosan; chlorhexidine; chlorhexidine gluconate; sodium hypochlorite; sodium stannate; hydrogen peroxide; carbamide peroxide; antibiotics; analgesics; chlorine dioxide; zinc-containing compounds and complexes; fluoride ion-providing compounds; enzymes and enzymatic compounds selected from lysozyme, lactoferrin, glucose oxidase, and lactoperoxidase; copper gluconate; natural plant extracts having anti-microbial or therapeutic properties; and mixtures thereof.

~~20. (Cancelled) A method of oral hygiene treatment as in claim 16 wherein said composition is a fluid or gel present in an amount sufficient to substantially moisten or to saturate said cotton roll, and each said cotton roll has a diameter ranging from about 3/16" to about 7/16", a length ranging from about 1" to about 2", a core of absorbent cotton fibers and a cotton fiber retaining sheath selected from a mesh braiding and a highly permeable woven or non-woven sheet material.~~

End of Section 2, Claim Amendments: